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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/000,172	11/30/2001	Jesse J. Twu	LJL 362	9507
23581	7590	03/29/2004	EXAMINER	
KOLISCH HARTWELL, P.C. 520 S.W. YAMHILL STREET SUITE 200 PORTLAND, OR 97204			CEPERLEY, MARY	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

**Application No.**

10/000,172

**Applicant(s)**

TWU, JESSE J.

**Examiner**

Mary (Molly) E. Ceperley

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 16 and 42-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 16 and 42-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                    |                                                                             |
|----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____                                                |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>01162004</u> .                                                            | 6) <input type="checkbox"/> Other: _____                                    |

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**1)** Page two of the specification is missing serial numbers. Correction is required.

**2)** An election of Group I, claims 1-12, 16 and 42-45, and the species defined by T = protein, P = polyhistidine, M = nickel and L = rhodamine was made **without** traverse in the response filed January 16, 2004. Claims 1-12, 16, and 42-45 are currently pending in this application.

**3)** Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

**4)** The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**5)** The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**6)** Claims 5-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the attachment of a luminophore through ionic bonding with a metal ion, does not reasonably provide enablement for covalent bonding of the luminophore to the metal ion. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The description of page 13, line 19 – page 14, line 14 of the specification states that "L incorporates one or more functional groups that associate with the metal ion M" to form a "coordination complex". Such "coordination

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complexes" with metal ion are well known in the art. However, there is no enabling written description of how to make a "luminophore" which was "covalently bound" to a metal ion.

**7)** Claims 1-12, 16 and 42-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of "compounds" wherein "T" is defined as being a member of a specific binding pair (specification: page 11, lines 16-22), does not reasonably provide enablement for any "T" which is not a member of a specific binding pair. The specification does not establish any utility for the claim 1 conjugate of a species with a luminescent label wherein the moiety "T" is not capable of functioning as a specific binding pair member. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

**8)** Claims 42-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description in the specification of the "kits" recited in these claims.

**9)** Claims 1, 5-12, 16 and 42-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the term "T" defined as a "labeled species" is confusing and renders the claim indefinite. Applicants state in their response to the restriction requirement that "the term "label" refers to the "-P-M-L" that is attached to the "T"". However, the claim, as written, appears to state that "T" itself contains a label in addition to the moiety "-P-M-L". To overcome this rejection, the claim should indicate that the term "labeled" refers to the moiety "-P-M-L".

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**10)** The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**11)** The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**12)** Claims 1-4, 11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterson (U.S. 5,840,834).

Peterson describes compounds which anticipate the compounds of instant claim 1. In the structure of col. 5, lines 10-26 of Peterson, the moiety "peroxidase" is also alternatively defined as a luminescent label such as "phycobiliprotein" or "luciferase" as described at col. 4, lines 36-40 of the patent. The complex of organic chelator and metal ion Ni of the structure of col. 4, is then further coupled to "any protein or amino acid sequence which contains a histidine tag" wherein "the polyhistidines on the protein or amino acid sequence bind very tightly to the Ni-NTA" complex. This final "complex" of the patent anticipates the "compound" of instant claim 1, i.e. "luciferase" and "phycobiliprotein" (in the position of "peroxidase") in the structure of the patent correspond to "L" of instant claim 1, "Ni" of the structure of the patent corresponds to "a metal ion" ("M") of instant claim 1, "histidine tag" of the structure of the patent corresponds to "P" of instant claim 1, and the "protein or amino acid sequence" (attached to the "histidine tag") of the structure of the patent corresponds to "T" of instant claim 1.

**13)** Claims 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterson (U.S. 5,840,834).

Peterson is applied for the reason stated in paragraph **12)** directly above. The packaging of reagents in kit form, as claimed, is an obvious expedient for ease and convenience in assay performance.

**14)** Claims 1-4, 11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ng et al (Langmuir (1995), Vol. 11, No. 10, pages 4046-4055). Ng et al describe luminescent metal complexes with his-tagged proteins which anticipate the "compounds" of instant claim 1. Structure **2** of page 4049 of the reference describes a chelate of copper with a fluorescent pyrene-substituted lipid. This chelate can be further attached to a his-tagged protein to form a complex (see the second column of page 4052, the last two sentences of the first paragraph under "**Discussion**"). This final complex anticipates the "compounds" of instant claim 1, i.e. "L" of instant claim 1 corresponds to the "pyrene" of the reference, "Cu" and "Ni" correspond to "M" of instant claim 1, "His" corresponds to "P" of instant claim 1, and "proteins" of ("his-tagged proteins") corresponds to "T" of instant claim 1. See also, page 4052, "**Fluorescence Microscopy of Bound Protein**".

**15)** Claims 42-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ng et al (see paragraph **14)** directly above).

Ng et al is applied for the reason stated in paragraph **14)** directly above. The packaging of reagents in kit form, as claimed, is an obvious expedient for ease and convenience in assay performance.

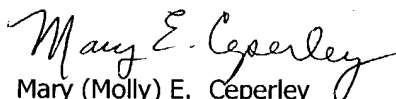
**16)** An inquiry of a general nature which is **not related to the prosecution on the merits** should be directed to Technology Center 1600 telephone number (571) 272-1600. The general fax number for the USPTO is (703) 872-9306.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823.

March 25, 2004

  
Mary (Molly) E. Ceperley  
Primary Examiner  
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